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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKETT NO.

EXAMINER	
ART UNIT	PAPER NUMBER
	Attachment to 27

DATE MAILED:

EXAMINER INTERVIEW SUMMARY RECORD

All participants (applicant, applicant's representative, PTO personnel):

(1) Mark Wilson (3) _____

(2) K Cochrane Carlson (4) _____

Date of Interview Oct 28, 1994

Type: ☒ Telephonic ☐ Personal (copy is given to ☐ applicant ☐ applicant's representative).

Exhibit shown or demonstration conducted: ☐ Yes ☐ No. If yes, brief description: _____

Agreement ☒ was reached with respect to some or all of the claims in question. ☐ was not reached.

Claims discussed: New Claims 56-80

Identification of prior art discussed: —

Description of the general nature of what was agreed to if an agreement was reached, or any other comments: See attached Examiner's Amendment to Claims

(A fuller description, if necessary, and a copy of the amendments, if available, which the examiner agreed would render the claims allowable must be attached. Also, where no copy of the amendments which would render the claims allowable is available, a summary thereof must be attached.)

☒ 1. It is not necessary for applicant to provide a separate record of the substance of the interview.

Unless the paragraph below has been checked to indicate to the contrary, A FORMAL WRITTEN RESPONSE TO THE LAST OFFICE ACTION IS NOT WAIVED AND MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW (e.g., items 1-7 on the reverse side of this form). If a response to the last Office action has already been filed, then applicant is given one month from this interview date to provide a statement of the substance of the interview.

☐ 2. Since the examiner's interview summary above (including any attachments) reflects a complete response to each of the objections, rejections and requirements that may be present in the last Office action, and since the claims are now allowable, this completed form is considered to fulfill the response requirements of the last Office action. Applicant is not relieved from providing a separate record of the substance of the interview unless box 1 above is also checked.

K. Cochrane Carlson
Examiner's Signature

PTOL-413 (REV. 2-93)

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EXAMINER INTERVIEW SUMMARY RECORD

All participants (applicant, applicant's representative, PTO personnel):

(1) Mark Wilson (3) ______

(2) K. Cochrane Carlson (4) ______

Date of interview 10-25-94

Type: ☒ Telephonic ☐ Personal (copy is given to ☐ applicant ☐ applicant's representative).

Exhibit shown or demonstration conducted: ☐ Yes ☒ No. If yes, brief description: ______

Agreement ☐ was reached with respect to some or all of the claims in question. ☐ was not reached.

Claims discussed: All pending in general

Identification of prior art discussed: USP 5,155,027

Description of the general nature of what was agreed to if an agreement was reached, or any other comments: MW telephoned to inquire about this application. IgG is dimerizing thus making a dimerizing rec ↑ affinity for the trimeric TNF. KCC will review prior art patent for obviousness. Also KCC will review Beutler declaration and scatchard plots submitted

(A fuller description, if necessary, and a copy of the amendments, if available, which the examiner agreed would render the claims allowable must be attached. Also, where no copy of the amendments which would render the claims allowable is available, a summary thereof must be attached.)

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Karen Cochrane Carlson PhD
Examiner's Signature

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Serial number 07/862495

Art Unit 1812

An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the Issue Fee.

Authorization for this Examiner's Amendment was given in a telephone interview with Mr. Mark Wilson on October 28, 1994.

Examiner's Amendment to the Specification

Change the title to: DNA encoding a chimeric polypeptide comprising the extracellular domain of TNF receptor fused to IgG, vectors, and host cells

On page 10, line 6, delete "in Table I".

On page 10, line 13, delete "TABLE I".

Examiner's Amendment to the Claims

Cancel Claims 1, 2, 4, 6-14, 16, 18-24, 27-29, and 36-46.

Add new Claims as follows:

56. An isolated DNA segment having a sequence encoding a chimeric polypeptide comprising the extracellular domain of a TNF receptor polypeptide functionally attached to a Fc portion and hinge region of an IgG heavy chain polypeptide.

57. The isolated DNA segment of Claim 56, where the TNF receptor polypeptide is a human TNF receptor polypeptide.

58. The isolated DNA segment of Claim 56, where the IgG heavy chain polypeptide is a mouse IgG polypeptide.

52

4 1
~~59~~. The isolated DNA segment of Claim ~~56~~, further incorporating a DNA segment encoding a specifically cleavable linker peptide functionally interposed between the TNF receptor polypeptide and the Fc portion.

5 4
~~60~~. The isolated DNA segment of Claim ~~59~~, where the specifically cleavable linker peptide comprises a thrombin-sensitive linker peptide.

6 1
~~61~~. A recombinant vector incorporating a DNA segment as defined by Claim ~~56~~.

7 6
~~62~~. The recombinant vector of Claim ~~61~~, where the TNF receptor polypeptide is a human TNF receptor polypeptide.

8 6
~~63~~. The vector of Claim ~~61~~, where the IgG heavy chain polypeptide is a mouse IgG polypeptide.

9 6
~~64~~. The vector of Claim ~~61~~, further incorporating a specifically cleavable linker peptide functionally interposed between the extracellular domain of the TNF receptor polypeptide and the Fc portion.

10 9
~~65~~. The vector of Claim ~~64~~, where the specifically cleavable linker peptide comprises a thrombin-sensitive linker peptide.

11 6
~~66~~. The vector of Claim ~~61~~, where the chimeric polypeptide encoding sequence is positioned adjacent to and under the control of an effective promoter.

12 11
~~67~~. The vector of Claim ~~66~~, where the promoter comprises a prokaryotic promot r, th vector being adapted for expression in a prokaryotic host.

13 ~~68~~. The vector of Claim 11 ~~66~~, where the promoter comprises a eukaryotic promoter, the vector being adapted for expression in a eukaryotic host, and the vector further includes a polyadenylation signal position 3' of the carboxy-terminal amino acid, and within a transcriptional unit of the encoding polypeptide.

14 ~~69~~. The vector of Claim 13 ~~68~~, where the eukaryotic promoter comprises a cytomegalovirus promoter.

15 ~~70~~. The recombinant host cell which incorporates an isolated DNA segment in accordance with Claim ~~56~~ 1.

16 ~~71~~. The recombinant host cell of Claim 15 ~~70~~, further defined as a eukaryotic host cell.

17 ~~72~~. The recombinant host cell of Claim 16 ~~71~~, further defined as a CHO cell.

18 ~~73~~. The recombinant host cell of Claim 15 ~~70~~, further defined as a prokaryotic host cell.

19 ~~74~~. The recombinant host cells of Claim 15 ~~70~~ where the DNA segment encoding a chimeric polypeptide is under the transcriptional control of regulatory signals functional in the recombinant host cell which regulatory signals appropriately control the expression of the chimeric polypeptide in a manner to allow all necessary transcriptional and post transcriptional modification.

20
~~75~~. A method of producing a chimeric polypeptide comprising the extracellular domain of the TNF receptor polypeptide functionally attached to a Fc portion and hinge region of an IgG heavy chain polypeptide, the method comprising:

(a) producing a recombinant host cell according to Claim ~~70~~ 15, such cell being capable of expressing the polypeptide;

(b) culturing the host cell under conditions appropriate for expressing the polypeptide; and

(c) recovering the chimeric polypeptide.

21
~~76~~. The method of Claim 20 ~~75~~, where additional steps comprise:

(a) cleaving the polypeptide at the specifically cleavable linker peptide; and

(b) recovering the polypeptide comprising an extracellular domain of the TNF receptor polypeptide.

22
~~77~~. The method of Claim 20 ~~75~~ wherein the host cell is a eukaryotic cell.

23
~~78~~. The method of Claim 22 ~~77~~ wherein the eukaryotic cell is a CHO cell.

24
~~79~~. The method of Claim 22 ~~77~~ wherein the eukaryotic cell is an insect cell.

25
~~80~~. The method of Claim 20 ~~75~~ wherein the host cell is a prokaryotic cell.

55